TAB X

SPENCER ABRAHAM
MICHIGAN

United States Senate

WASHINGTON, DC 20510-2203

September 6, 2000

The Honorable Donna E. Shalala
Secretary of Health and Human Services
200 Independence Ave., SW
Washington, DC 20201

Dear Madam Secretary:

I wish to express my strongest opposition to the changes in Medicare reimbursements for cancer-fighting drugs, as issued in the April 7th, 2000 *Federal Register*. These changes, in my opinion, will decimate the outpatient cancer care industry, drastically reduce the number of available cancer care facilities, force longer waits and further travel for cancer patients, and ultimately, result in higher mortality from cancer, at the same time that our medical researchers are beating back this deadly disease with new discoveries and treatments that have markedly improved cancer survival rates.

Besides serving as a clarion call as to the dangers of government price-fixing for any drugs, this specific action is proof-positive that the regulatory issuance procedures used by the Health Care Financing Administration must be changed if health care providers are going to be able to give quality health care to our nation's Seniors. To unilaterally issue such a rule, outside of the normal regulatory process, so as to avoid, in your words, "undergoing the formal rule-making process," appears to me to violate Section 1871(a) of the Social Security Act, as well as the intent of the Administrative Procedures Act.

Therefore, I urge you to reverse this decision, and instead review the entirety of Medicare's reimbursement policies for cancer treatment, including adequate reimbursement rates for the myriad of necessary treatments whose cost are not covered by appropriate codes under either the current or new reimbursement regime.

Of particular concern to me is the decision to establish by Executive fiat the reimbursement rates for a number of oncological drugs -- price-fixing if you will. As I understand the new rule, these drug reimbursement rates will be based upon an Average Wholesale Price (AWP) developed by the Department of Justice in pursuit of an fraud lawsuit, and not the Red Book, First Data Bank, or other accepted industry standards for determining AWP. ELM Services, Inc. recently conducted a survey of the impact of these government fixed prices on the cancer care industry, and I found it particularly noteworthy that none of the hospitals, cancer care centers, or oncologists surveyed were able to obtain drugs at even the wholesale price quoted by the Department of Justice, let alone at 95% of AWP. Considering that Justice was unwilling (or unable) to discuss its methodology in determining these AWP figures, these two unanswered questions would seem to cast the entire Department of Justice data in doubt, and thereby HCFA's new reimbursement rates. Given that all previous HCFA regulations have referenced accepted industry-wide data for determining AWP, this dramatic departure is particularly disconcerting to me, as I hope it will be to you.

As you know, Congress laid down very clear legislation regarding these reimbursements in the Balanced Budget Act of 1997, where it instructed HCFA to base these reimbursement rates at 95% of the average wholesale price (assumed to be an industry-accepted AWP, not one derived by government bureaucrats, and then withheld from the public). This was done, as I understand, not only to protect the integrity of the market, but also to ensure that cancer care providers would receive adequate reimbursements for the care they provide. Again, however, the ELM Services analysis paints a chilling picture where Seniors are denied cancer care, or can't get to it, and will therefore suffer higher mortality rates because of this action.

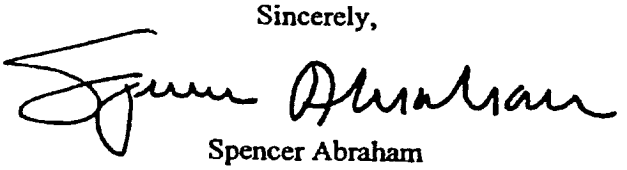
But even this AWP data appears seriously flawed in that it was apparently did not include the new therapeutic drugs that came available in 1996 (Justice's survey year). When the costs of these new drugs is added to the AWP totals, the high margins that apparently led HCFA to propose these cuts suddenly disappear. This would appear to convincingly support the contention of the ELM Services study that "the actual costs to hospitals for providing chemotherapy and supportive care, documented in the finalized Medicare cost reports, was equivalent to the Average Wholesale Price minus 5 percent (AWP-5%) [or 95% of AWP as I have referenced]."

The end result, I fear is a dramatic and sudden loss of access to cancer care for Medicare beneficiaries. If hospitals, with their higher volumes and greater ability to absorb incidental losses, are only breaking even with reimbursement at 95% of AWP, this additional round of reimbursement cuts would seem to be particularly unsustainable, especially since two-thirds of all hospitals in Michigan have already cut services due to lower Medicare reimbursements. For the cancer care clinics and oncologists who provide cancer care on a much lower volume, and without the infrastructure support of a hospital, the situation can only be dramatically worse. ELM Services had the Lewin Group and Orion Consulting simulate the impact of HCFA's new reimbursement rates, and they determined that "A reduction in payment for oncology drugs – without an offsetting increase in other fees to physicians and hospitals – will eliminate the current provider network in oncology as well as 95% of the infrastructure for clinical cancer research."

Madam Secretary, we all wish to ensure that Medicare costs are contained as strictly and as closely as possible. But these reimbursement cuts make continued care for Medicare beneficiaries financially unviable. I am concerned that since the elderly are 50-65% of the current cancer care population, such a dramatic cut on the part of HCFA would destroy access to cancer care for all Americans.

I implore you to rescind this policy.

Sincerely,



Spencer Abraham
United States Senate